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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,649	08/18/2003	Jack Chu	PA1515 (MEDT/0018)	5247

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EXAMINER	
NEAL, TIMOTHY J	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,649	CHU ET AL.	
	Examiner	Art Unit	
	Timothy J. Neal	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 31-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 31-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendments filed on 8/13/2007 and the Request for Continued Examination filed on 9/04/2007.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-29 and 31-48 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. The Applicant has submitted evidence (US 5,147,370) stating that nitinol does not compress after implantation. With this evidence, the Applicant's invention is not operable. There is no explanation in the Applicant's disclosure that adequately describes the differences between the materials used in the claimed device and the prior art materials. Therefore, the claimed device is inoperable because the Applicant's evidence shows the device is not capable of contracting after it has been implanted, as required by the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-29 and 31-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Applicant continues to argue that the prior art stents are not capable of contracting when the aneurysm site contracts because the materials are not capable of the function. The Examiner notes that the Applicant's stent is made from the same materials as the prior art. This rejection is deemed appropriate because the Applicant's disclosure fails to state the differences between the known materials and the claimed stent. The Examiner is not sure if the Applicant has invented a new type of nitinol that behaves in a manner that is inconsistent with the prior art. The Applicant has referenced in the arguments patent 5,147,370 stating that nitinol is incompressible after implantation. The Applicant needs to address the differences between the claimed nitinol and this known nitinol because the Examiner cannot determine what feature of the claimed invention causes the claimed function.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6, 7, 17-19, 40-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Jansen et al. (US 6,579,308).

Jansen discloses an intravascular treatment device, comprising: a contractable stent (2) locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing, and comprises at least one therapeutic agent (Column 2 Lines 49-50). The stent is helical, self-expanding, comprises nitinol, and the stent is deployed by catheter to an aneurysm site (see figures 1-4 and disclosure). Claim 40 is a product-by-process claim and does not result in a different structure, thus not overcoming the prior art. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Once a product appearing to be substantially identical is found, the burden shifts to the Applicant to show an unobvious difference.

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. (U.S. 6,096,070).

Regarding **claim 43**, Ragheb et al. discloses a helical contractable stent locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts due to healing, and comprises at least one therapeutic agent (Col 19 Lines 22-27, Col 6 Lines 39-42 and Col 15 Line 56).

Regarding **claim 44**, Ragheb et al. discloses the stent being biodegradable (Col 7 Lines 29-47).

Regarding **claim 45**, Ragheb et al. discloses the stent comprises poly(orthoester) (Col 7 Lines 29-47).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Maass (US 4,553,545) or Segal (US 5,755,708) or Summers et al. (US 5,772,668) or Melzer et al. (US 6,280,385).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose double or triple helices. Maass, Segal, Summers, and Melzer disclose stents with double helix configurations (see figures of references). Melzer in particular discloses multiple helix configurations. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's single helix to include double or triple helices. Such a modification would provide more coverage of the target site, increased surface area for the deliver of drugs, and other advantages as known in the art.

Claims 8, 9, 11, 12, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Ragheb '070.

Jansen discloses the invention substantially as claimed as stated above. Jansen further discloses the stent comprises a polymer (polyesters and polyurethane) as recited in claims 9 and 12. Jansen is silent on whether these polymers are biodegradable or not. Jansen does not explicitly disclose a therapeutic agent. Ragheb teaches a therapeutic agent (Col 19 Lines 22-27, Col 6 Lines 39-42 and Col 15 Line 56). Ragheb teaches that a variety of conventional materials can be employed as a base material for a stent, including biodegradable and non-biodegradable materials (Col 7 Lines 18-27). Jansen discloses the polymers for the stent as stated above. Jansen does not disclose the nature of the materials. However, because Ragheb teaches that conventional polymers are known to be either biodegradable or non-biodegradable, the Examiner considers it obvious to modify Jansen's polymers to be either biodegradable

or non-biodegradable and to include drugs. Such a modification would in the biodegradable case allow the stent to degrade and thus not need to be removed. If the stent is required to remain within the body indefinitely, a non-biodegradable polymer should be used. Placing drugs at the treatment site reduce inflammation, prevent clot formation, and may have additional benefits as known in the art.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Ragheb '070 as applied to claim 8 above, and further in view of by Wright et al. (US 6,273,913).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose the therapeutic agent being covalently linked to the polymer. Ragheb teaches covalently bonding heparin to the outermost surface of the stent (Col 8 Line 25). When this teaching is applied to Jansen, this heparin would be the therapeutic coating on the outside of the stent. The heparin then helps prevent clot formation. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's stent to include Ragheb's covalent heparin. Such a modification would prevent clot formation. The Examiner also notes that Ragheb teaches the more general principle of using covalent bonds to link drugs to polymers. This teaching can be applied to Jansen when other drugs are to be administered. Basically, the concept is not limited to heparin. Wright teaches that drugs (specifically rapamycin) may be bound to a stent covalently via the Carmeda process (Col 5 Line 65 through Col 6 Line 10). Therefore, it would have been obvious

to a person having ordinary skill in the art at the time the invention was made to use covalent linking to bind the therapeutic agent to the polymer stent. Such a modification provides a strong link to the polymer to allow for the release of the drug as desired based on the application.

Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Eisert (US 2005/0192664) and Hunter et al. (US 6,333,347).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose the polymer being pH-sensitive and the polymer being temperature sensitive. Eisert teaches a pH sensitive polymer (Paragraph 64) that expands when contacted with a certain pH. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s polymer stent to include Eisert's pH-sensitive polymer. Such a modification would allow the stent to expand. Hunter '347 teaches that cellulose acetate phthalate is a pH sensitive polymer (Col 7 Lines 27-58). Therefore, it would have been obvious to use cellulose acetate phthalate as Eisert's pH-sensitive polymer.

Eisert teaches a temperature sensitive polymer (Paragraph 65) that takes on a new shape when heat is applied. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Ragheb et al.'s polymer stent to include Eisert's temperature sensitive polymer. Such a modification would allow the stent to change shape upon application of heat. Hunter '347 teaches that pluronics F-127 is a temperature sensitive polymer (Col 8 Lines 41-

65). Therefore, it would have been obvious to use pluronics F-127 as Eisert's temperature-sensitive polymer.

Claims 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Narciso, Jr. (US 5,419,760).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose the specific type of therapeutic agent used. Narciso, Jr. teaches the application of aspirin to a stent to act as an anti-platelet/anti-thrombus drug (Col 5 Lines 55-68). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's stent to include Narciso's aspirin. Such a modification would reduce clot formation.

Claims 28, 29, 31-39, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Hunter et al. (US 5,716,981).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose wherein the therapeutic agent is contained in microspheres. Hunter '981 teaches polymer microspheres made of polyvinyl alcohol (PVA) and size ranges of up to approximately 120 microns (figures 5-6, 9-10), release profiles of the therapeutic agent including about 1% to about 25% of the therapeutic agent released in the first 10 days (figure 15D), and the coating being a spray from microspheres (17 Lines 7-67 through Col 18 Lines 1-7). Therefore, it would have been obvious to a person having ordinary skill in the art to modify Jansen's stent to include Hunter's

microspheres and release profile. Such a modification would allow for a controlled release of a desired amount to the target site.

Claims 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Ragheb '070 further in view of Vallana et al. (US 2003/0028242) and Hunter '981.

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose wherein the therapeutic is applied as a coating the coating further comprising a polymer, the nature of the application of the coating, a second coating, two therapeutic coatings, the polymer coating being biodegradable, and wherein the coating is time-released. Ragheb teaches the therapeutic agent being applied as a coating to the stent (Abstract and Column 7 Lines 55-62); the coating being applied as a film (Col 18 Line 2); a second coating deposed over the therapeutic coating (Fig. 2 Item 20); at least two therapeutic coatings, wherein each therapeutic coating is separated by a second coating (Fig. 2 Items 18, 22, and 24); the coating being a biodegradable coating (Col 9 Lines 20-67); the polymer being heparin (Col 9 Line 23); the coating being a time release coating (Col 10 Lines 30-35). Multiple coating allow for multiple drugs to be released or the same drug to be released with different time-release characteristics. Ragheb does not disclose the therapeutic coating further comprising a polymer. Vallana teaches that polymers are used as carriers for therapeutic coatings (Paragraph 65). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify

Jansen's stent to include Ragheb's coating inlcuding Vallana's polymer. Such a modification provides the advantage of additional control over the release characteristics of the drug. Furthermore, the polymer carrier coating of Vallana is considered a time-release coating being that the therapeutic agent is released over time. It is also noted that Hunter '981 discloses a polymer carrier as stated above. The combination of Hunter '981, Ragheb, and Jansen would apply in the same manner as the combination of Ragheb, Vallana, and Jansen.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Clouse (US 5,211,658).

Jansen discloses the invention substantially as claimed as stated above. Jansen does not explicitly disclose the method including a stent graft, and wherein the therapeutic agent is inactive until activated. Clouse teaches first inserting a stent to an aneurysm site and then inserting a graft (Col 3 Line 46 through Col 4 Line 13). This shows that it is known to deliver a stent before delivering the graft with the stent between the graft and the aneurysm. The Clouse reference discloses the graft traversing the aneurysm in order to prevent pressure on the aneurysm. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's method to include Clouse's stent graft. Such a modification would prevent pressure on the aneurysm from blood flow. Obviously, Jansen's stent would need to be inserted before Clouse's. If not, Jansen's stent would not be able to be located so that it engages the aneurysm. Jansen's stent would act in

a similar manner to vaso-occlusive coils and provide drug treatment and other advantages to the aneurysm site.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen '308 in view of Clouse (US 5,211,658) as applied to claim 46 above, and further in view of Falotico et al. (US 2003/0060877).

Jansen and Clouse disclose the invention substantially as claimed as stated above. They do not explicitly disclose the method wherein the therapeutic agent is inactive until activated. Falotico teaches a therapeutic agent being inactive until it comes in contact with an activating agent (Paragraph 142). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Jansen's agent to include the therapeutic agent and the activation characteristic of Falotico. Such a modification would allow for additional measure of time release.

Response to Arguments

Applicant's arguments filed 8/13/2007 have been fully considered but they are not persuasive.

The Applicant has argued that Jansen does not disclose a stent that is contractable because nitinol is not contractable after it has been set above the TTR. The Examiner notes that the Applicant's invention is made from nitinol. Also, Jansen discloses that the stent may be made from stainless steel, which does not have the

exact same characteristics as nitinol. The Applicant needs to show that the materials claimed are different from the prior art materials. The Applicant's referenced prior art contradicts the Applicant's invention. Clarification is required. Also, Jansen's recitation that the wire is of a sufficient hoop strength and diameter so that it may be placed in a vessel without distending the vessel suggests that the device does not have sufficient strength to expand the vessel. Drawing the conclusion that the wire is not contractable is not supported by the disclosure. Regarding Ragheb, the ability of a stent to prevent abrupt closure is not the same as saying that it is incapable of contracting. The healing process is considerably more gradual. Again, the Ragheb device is made from the same materials as those claimed. The arguments that the references used in combination with Jansen teach away from the claimed device are not persuasive because the elements used in the combination are not attempting to address the limitations of claim 1, 42, or 43. The teachings of drug coatings, microspheres, and particular materials are separate from the stent structure of Jansen. All other arguments are based on the alleged deficiencies in Jansen, which has been addressed above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

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